IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MONTANA

BILLINGS DIVISION

TOBY C. MCADAM, Plaintiff, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET A. HAMBURG, COMMISSIONER OF FDA, Defendants.	CV 12-137-BLG-SEH-CSO FINDINGS AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

I. Introduction

On February 25, 2013, Defendants filed a "Motion to Dismiss Complaint." *ECF 3*. Plaintiff Toby C. McAdam ("McAdam") did not timely respond to the motion, despite being granted extensions of time in which to do so. *See ECF 9, 15*.

On September 25, 2013, as previously noticed *(ECF 15)*, the Court held a hearing on Defendants' Motion. McAdam did not appear. The Court heard argument from Defendants' counsel and testimony from

Lisa Lathar, Compliance Office in the Seattle District Office of the United States Food and Drug Administration.

On September 26, 2013, McAdam filed a response *(ECF 20)* to Defendants' Motion to Dismiss and, incredibly, a request for hearing on the Motion to Dismiss – despite his failure to appear at the hearing on said motion the previous day.

II. Background Facts

The evidence presented by Defendants indicates that McAdam has been making and selling unapproved drugs for cancer and other serious diseases for approximately eight years. *See ECF 3 and attachments; United States v. Toby Carl McAdam*, Cause No. CV-10-128-BLG-SEH-CSO. This evidence is summarized below.

In 2006, the FDA issued Greta Armstrong a Warning Letter that Risingsun was advertising unapproved cancer remedies on the websites www.risingsunhealth.com and www.bloodrootproducts.com, and warned her that selling unapproved products for use in the cure, mitigation, treatment, and prevention of disease violated the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act"). The FDA also advised that the products advertised on the website were

misbranded under the Act and did not contain adequate directions for usage. After receipt of that FDA Warning Letter, McAdam informed the FDA by telephone that he was the owner of Risingsun and he would remove the offending drug claims from the websites. McAdam followed up with a letter to the FDA shortly thereafter stating that he would remove the offending drug claims.

FDA investigators inspected Risingsun between November 27 and 29, 2007, and discovered that McAdam's violations of the Act were ongoing. McAdam wrote two more letters promising that he would cease his illegal activity. Despite this, on April 4 and 10, 2009, FDA investigators noted that Risingsun's websites and many of their product labels still contained illegal drug claims that its products could cure, mitigate, treat, or prevent disease.

In May and June 2010, FDA made numerous undercover purchases of Risingsun's products and found that McAdam continued to sell illegal unapproved new drugs which FDA had previously informed McAdam was in violation of 21 U.S.C. §§ 352(f)(1) and 355(a). These purchases were shipped from Montana to undercover investigators located in Maryland, Arizona, and Washington State.

On October 13, 2010, the United States filed a Complaint against McAdam under the injunction provisions of the Act, 21 U.S.C. § 332(a) ("Enforcement Case"). *See United States v. Toby Carl McAdam*, *supra, at ECF 1*.

The Complaint alleged, among other things, that McAdam regularly sold unapproved drugs in interstate commerce to treat serious diseases such as cancer, anemia, asthma, ADD/ADHD, arthritis, epilepsy, and intestinal parasites. *Id*. These drugs were alleged to be "new drugs," as defined by 21 U.S.C. § 321(p)(1), in that they were not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. *See CV-10-128-BLG-SEH-CSO, ECF 1*.

The Complaint alleged that McAdam violated 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce such unapproved drugs in violation of 21 U.S.C. § 355. *See CV-10-128-BLG-SEH-CSO, ECF 1*. The Complaint also alleged that McAdam sold new animal drugs, as defined by 21 U.S.C. § 321(v)(1), that were

unapproved by the FDA, and which were unsafe within the meaning of 21 U.S.C. § 360b(a) and adulterated within the meaning of 21 U.S.C. § 351(a)(5). *See CV-10-128-BLG-SEH-CSO, ECF 1.*

Furthermore, the Complaint alleged that McAdam's drug products were misbranded within the meaning of 21 U.S.C. § 353(b)(1) because they were prescription drugs, the distribution of which without a prescription resulted in the drug being misbranded while held for sale, and within the meaning of 21 U.S.C. § 352(f)(1), because their labeling failed to bear adequate directions for use. *See CV-10-128-BLG-SEH-CSO, ECF 1.* The introduction of adulterated and misbranded new animal drugs into interstate commerce is prohibited under 21 U.S.C. § 331(a).

Significant to these Findings and Recommendation the parties were able to reach an agreement in the Enforcement Case and filed a negotiated Consent Decree of Permanent Injunction ("Consent Decree"). *See CV-10-128-BLG-SEH-CSO, ECF 5.* McAdam was represented by counsel in his negotiations with Defendants.

The Consent Decree enjoined McAdam from: introducing into interstate commerce, holding for sale after shipment in interstate

commerce, and manufacturing, processing, packaging, labeling, holding, selling, and distributing a broad range of products, including, inter alia, (a) any topically-applied product for human or animal use containing extracts or components of the Bloodroot or Graviola plants, (b) any "new drug," (c) any "new animal drug," and (d) any dietary supplement, unless and until (i) the FDA approves a new drug application or abbreviated new drug application for the product pursuant to 21 U.S.C. § 355, or (ii) the FDA approves an investigational new drug application for the product pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. 312, or (iii) the FDA approves a new animal drug application or abbreviated new animal drug application for the product pursuant to 21 U.S.C. § 360b(b) or such product meets the requirements for the investigational new animal drug exemption pursuant to 21 U.S.C. § 360b(j). *See CV-10-128-BLG-SEH-CSO, ECF 5.*

Second, the Consent Decree required that McAdam demonstrate to the FDA that the new drug is the subject of a valid FDA approval before manufacturing or distributing any new drug. *Id.*

Third, the Consent Decree required McAdam to retain a "labeling expert." *Id.*

Fourth, the Consent Decree generally enjoined McAdam from introducing unapproved, misbranded, and/or adulterated human and animal drugs into interstate commerce, or causing the adulteration or misbranding of such products held for sale after shipment in interstate commerce. *Id*.

The Consent Decree specifically addresses future violations and states that in the case of future violations of the Consent Decree, the Act, or the FDA's regulations, the "FDA may, as and when it deems necessary in its sole discretion, direct [McAdam], in writing, and order [McAdam] to take appropriate corrective action. . . ." Such corrective action may include an order to "[c]ease manufacturing, processing, packaging, labeling, holding, selling, and/or distributing any or all drugs and/or dietary supplements," or "any other corrective action(s) as FDA deems necessary to protect the public health or to bring [McAdam] and [his] products into compliance with the Act, applicable regulations, and this [Consent] Decree." *Id*.

In addition, the Consent Decree orders that McAdam will pay monetary damages if they violate the Consent Decree, attorney's fees in a contempt action, and the costs of "all FDA inspections, investigations,

supervision, reviews, examinations, and analyses specified in [the Consent Decree] or that FDA deems necessary to evaluate [McAdam's] compliance" at the standard prevailing rates. *Id.*

The Consent Decree further provides that "[a]ll decisions specified in this [Consent] Decree shall be vested in the discretion of FDA and shall be final and [McAdam] shall abide by the decisions of FDA." If contested, the Consent Decree provides that the FDA's decisions "shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A)." *Id.*

On September 15, 2011, the FDA notified McAdam that Risingsun was in violation in the Consent Decree and ordered McAdam to cease operations until he could demonstrate compliance with the Consent Decree. From February 14 through February 16, 2012, the FDA conducted an inspection at Risingsun. The FDA's inspection revealed that, notwithstanding the FDA's September 15, 2011 notification of non-compliance, McAdam continued to sell products in violation of the Consent Decree.

Following the February 2012 inspection, McAdam faxed to the FDA a letter dated March 5, 2012, which indicated that he would

address the observed deficiencies in the near future. McAdam, however, has not followed up on this assurance and has not submitted a corrective action plan that was later requested by the FDA. Furthermore, on March 29, 2012, the FDA sent an invoice of $1,524.39, pursuant to Paragraph 12 of the Consent Decree, to reimburse the Agency for the cost of the February 2012 inspection. McAdam has not paid this invoice.

Following his receipt of the September 15, 2011 notice, and just prior to the February inspection, McAdam filed a "Request to Set Aside Consent Decree and Preliminary Injunction" on February 14, 2012. *See CV-10-128-BLG-RFC, ECF 8*. McAdam's request alleged that he had been coerced and intimidated into signing the Consent Decree, that he should not be required to hire a labeling expert because "there is no criteria nor certification procedures for a person to become a label specialist," and that the Consent Decree violates his rights to equal protection. On March 8, 2012, Judge Cebull denied McAdam's motion in full. *See CV-10-128-BLG-RFC, ECF 12*.

The FDA sent McAdam another letter on April 20, 2012, notifying him that he was continuing to violate the Consent Decree, pointing out

that the FDA had observed several additional violations of the Consent Decree. McAdam did not respond. The FDA sent him yet another letter on July 27, 2012, requesting that he pay liquidated damages in the amount of $80,000 because of his ongoing violations of the Consent Decree and the Act. McAdam did not pay the liquidated damages request.

McAdam filed on September 11, 2012, a motion entitled "Request for Hearing to Compel [Defendants] to Specify Criteria as to What is Not a Medical Claim and to Clarify Criteria Standards Set for So Called Label Specialist and For this Court to Review and Determine If [McAdam] Has Infect (sic) Complied With Decree." *See CV-10-128-BLG-RFC, ECF 13.* Judge Cebull denied this request, noting that it raised the exact arguments that this Court had previously rejected. *Id. at ECF 16.*

On October 17, 2012, the FDA conducted an inspection of Gesunheit! Nutrition Center in Bozeman, Montana, and found further evidence that McAdam was in violation of the Consent Decree.

On October 19, 2012, McAdam filed the Complaint in the instant matter, arguing that the Consent Decree violates his right to equal

protection (Counts I, III & IV). He also invoked a "right of choice" ostensibly provided by the Constitution (Count II), and alleged that the FDA's actions with respect to him have "put the health and safety of the general public at risk." (Count V). *ECF 1*.

On October 31, 2012, an attorney from the FDA's Office of the Chief Counsel informed McAdam via letter that his case had been referred back to his office to consider whether to bring further court proceedings, and that, in the absence of immediate compliance with the Consent Decree, the FDA would refer this case back to the Department of Justice to file a motion with the Court seeking an award of liquidated damages under Paragraph 7 of the Consent Decree. In response, McAdam filed a sworn affidavit dated November 8, 2012, stating that he "will cease operations." *See CV-10-128-BLG-RFC, ECF 17*.

On February 22, 2013, the United States filed a Petition in *CV-10-128-BLG-SEH-CSO*, seeking an order to show cause why McAdam should not be held in civil contempt for violating the terms of the Consent Decree as well as a motion for liquidated damages. *See CV-10-128-BLG-RFC, ECF 18 & 19*. On September 25, 2013, this Court granted the motion for order to show cause, setting a hearing for

McAdam to show cause on October 24, 2013, and ordering liquidated damages in the amount of $80,000. *See CV-10-128-BLG-RFC, ECF 34 & 35.*

III. Standard of Review

To be sustained under Rule 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim has "facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009) (citing *Twombly*, 550 U.S. at 556).

However, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citation omitted). A court need not accept "legal conclusions" as true. *Iqbal*, 556 U.S. at 679.

Although the court is bound to pay certain deference to factual allegations, it is not proper for the court to assume that "the [plaintiff] can prove facts which [he or she] has not alleged." *Assoc. Gen.*

Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 526 (1983). Nor must the court "accept as true allegations that contradict matters properly subject to judicial notice or by exhibit" or those which are "merely conclusory," or require "unwarranted deductions" or "unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001) (citation omitted), amended on other grounds, 275 F.3d 1187.

IV. Analysis

The Complaint in this matter seeks primarily to amend the terms of the Consent Decree in *CV-10-128-BLG-RFC*, on grounds that have already been denied by Judge Cebull twice. *See CV-10-128-BLG-RFC, ECF 8 & 12.*

McAdam's attempt to modify the Consent Decree through this independent action is prohibited and must be dismissed under Rule 12(b)(6). The Consent Decree specifically provides that any attempt to modify its terms should be addressed in the context of the Enforcement Case. Paragraph 20 of the Consent Decree specifically states: "This Court retains jurisdiction of this action for the purpose of enforcing or modifying this [Consent] Decree and for the purpose of granting such

additional relief as may be necessary or appropriate." *See CV-10-128-BLG-RFC, ECF 5.*

In his Complaint, McAdam alleges in his prayer for relief that he is entitled to damages against Defendants based on alleged violations of his Constitutional rights. *ECF 1.* Specifically, he claims that he is entitled to damages of $8,000 per month to compensate him for lost revenue relating to a drug which he agreed in the Consent Decree he would not manufacture or distribute, and $3,600 to compensate him for having retained a "so called label expert." *ECF 1.*

McAdam's attempt to obtain damages against Defendants is an impermissible collateral attack on the Consent Decree. It is implausible that the United States could be subject to liability for damages based on the judgment the Court entered in the Enforcement Case because to award the damages sought by McAdam would effectively be to vacate the Consent Decree. This Court has twice already refused to modify or vacate the Consent Decree based on identical arguments. *See CV-10-128-BLG-RFC, ECF 8 & 12.*

Furthermore, McAdam has failed to allege any exception to sovereign immunity that provides a basis for damages against the

United States, and this Court is therefore without jurisdiction over McAdam's claim for damages. The United States is a sovereign, and may not be sued for money damages without its consent. *United States v. Testan*, 424 U.S. 392, 399 (1976).

The United States has not waived its sovereign immunity for actions seeking damages for constitutional violations. *See Holloman v. Watt*, 708 F.2d 1399, 1401-02 (9th Cir. 1983) (sovereign immunity not waived for claim under the Constitution for damages against the United States); *Arnsberg v. United States*, 757 F.2d 971, 980 (9th Cir.1984) (same). Counts I through IV of the Complaint are expressly and solely premised on alleged violations of McAdam's constitutional rights, and his claims for damages should therefore be dismissed with prejudice.

Finally, McAdam's Complaint also is subject to dismissal because it is barred by the res judicata doctrine. "Res judicata" refers to the preclusive effect of prior litigation and falls into two categories: claim preclusion and issue preclusion. *Robi v. Five Platters, Inc.*, 838 F.2d 318 (9th Cir. 1988). "An action is barred under res judicata where (1) the prior litigation involved the same parties or their privies, (2) the

prior litigation was terminated by a final judgment on the merits, and (3) the prior litigation involved the same 'claim' or 'cause of action.'" *See Hydranautics, Inc. v. Filmtec Corp.*, 204 F.3d 880, 887-88 (9th Cir. 2000), citing *Blonder-Tongue Labs. v. Univ. of Ill. Found.*, 402 U.S. 313, 323-24 (1971).

Here, the prerequisites for res judicata are satisfied. All of the claims raised in the instant action could have been raised as defenses in the Enforcement Case. Most of them were resolved by this Court against McAdam through his two post-decree motions. *See CV-10-128-BLG-RFC, ECF 8 & 12.*

V. Conclusion

McAdam fails to plead any claim upon which relief may be granted, and his claim for damages is without merit. Moreover, sovereign immunity bars monetary damages against Defendants in this case. McAdam's claims should also be dismissed because they are barred by the doctrine of res judicata.

Therefore, based upon the foregoing, IT IS RECOMMENDED that Defendant's Motion to Dismiss Complaint (*ECF 3*) be GRANTED and the Complaint (*ECF 1*) be DISMISSED WITH PREJUDICE.

NOW, THEREFORE, IT IS ORDERED that the Clerk shall serve a copy of the Findings and Recommendation of United States Magistrate Judge upon the parties. The parties are advised that pursuant to 28 U.S.C. § 636, any objections to the findings and recommendation must be filed with the Clerk of Court and copies served on opposing counsel within fourteen (14) days after service hereof, or objection is waived.

DATED this 30th day of September, 2013

/s/ Carolyn S. Ostby
United States Magistrate Judge